Remarks

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

Claim 1 has been amended, claims 12, 109–144, and 184 have been cancelled, and new claim 185 has been added. Descriptive support for new claim 185 is provided in claim 10 as originally filed. No new matter has been added. Claims 1–11, 13–16, 145–183, and 185 are pending, with claims 145–183 being withdrawn.

The withdrawal from consideration of claims 180–183 is respectfully traversed. Applicant hereby requests reconsideration of the withdrawal of claims 180–183, which are directed the specific species of the polypeptide monobody of claim 1. Alternatively, to the extent that claim 1 is now allowable for the reasons discussed below, claims 180–183 should be rejoined with claim 1. Applicant further requests rejoinder of claims 145–179 because each of these method claims recites the use of a "polypeptide monobody according to claim 1." *In re Ochiai*, 71 F.3d 1565, 37 U.S.P.Q.2d 1127 (Fed. Cir. 1995).

The rejection of claims 1–16 for obviousness-type double patenting over claim 1 of U.S. Patent No. 6,673,901 to Koide ("Koide") is respectfully traversed.

Claim 1 of Koide relates to a fibronectin type III (Fn3) polypeptide monobody. The polypeptide monobody includes at least two Fn3 β-strand domain sequences with a loop region sequence linked between each Fn3 β-strand domain sequence. At least one monobody loop region sequence varies as compared to the wild-type (SEQ ID NO:110) loop region sequence by deletion of two to twelve amino acids in the loop region sequence, insertion of at least two to 25 amino acids, or replacement of at least two amino acids in the loop region sequence, and the polypeptide monobody loop region comprises at least two amino acids and binds to a specific binding partner (SBP) to form a polypeptide:SBP complex.

The United States Patent and Trademark Office ("PTO") has taken the position that the present claim is obvious over Claim 1 of Koide, merely because the claims have a genus-species relationship. This is insufficient to establish a *prima facie* case of obviousness. *See In re Baird*, 16 F.3d 380, 382, 29 U.S.P.Q.2d 1550, 1552 (Fed. Cir. 1994) ("The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious."). The PTO has failed to assert (let alone

establish) a motivation to modify the claimed polypeptide monobodies of Koide such that they have nuclear receptor binding affinity. Thus, claim 1 of Koide, while generic, does not teach or suggest the species presently claimed. Accordingly, the rejection of claims 1–16 for obviousness-type double patenting over Koide is improper and should be withdrawn.

The rejection of claims 1–16 under 35 U.S.C. § 112 (1st para.) for lack of enablement is respectfully traversed in view of the above amendments. The PTO has acknowledged at pages 6–7 of the outstanding office action that claimed monobodies derived from SEQ ID NOs: 2 and 3 are fully enabled. Therefore, this rejection should be withdrawn.

The rejection of claims 1–16 under 35 U.S.C. § 112 (1st para.) for lack of written description is respectfully traversed in view of the above amendments. The PTO has acknowledged at page 11 of the outstanding office action that claimed monobodies derived from SEQ ID NOs: 2 and 3 satisfy the written description requirement. Therefore, this rejection should be withdrawn.

Moreovcr, applicant submits that new claim 185 is fully cnabled and satisfics the written description requirement.

Claim 185 relates to a fibronectin type III (Fn3) polypeptide monobody comprising β-strand domain sequences A through G of a tenth Fn3 domain of fibronectin, and loop region sequences AB, BC, CD, DE, EF, and FG. At least one loop region sequence selected from the group of AB, BC, FG, and combinations thereof, varies by deletion, insertion, or replacement of at least two amino acids from a corresponding loop region in the tenth Fn3 domain of fibronectin, and the polypeptide monobody exhibits nuclear receptor binding activity. As noted in the amendment filed March 31, 2006, and the accompanying Declaration of Shohei Koide under 37 CFR § 1.132 ("Koide Decl."), mammalian tenth Fn3 domains of fibronectin are highly conserved, particularly at the β-strand regions; therefore, the structural integrity of the β-strands is maintained in the starting scaffold of the claimed monobodies. Koide Decl. ¶¶ 5, 10. The AB, BC, and/or FG loops may be modified, *e.g.*, to confer nuclear receptor binding affinity, as claimed, without compromising the monobodies' stability. Present Application at Examples 1–6; Batori et al., "Exploring the Potential of the Monobody Scaffold: Effects of Loop Elongation on the Stability of Fibronectin Type III Domain," *Protein Engineer'g* 15(12):1015–1020, 1019 (2002) (attached hereto as Exhibit 1). The present application clearly teaches how to construct a library of polypeptide monobodies by modifying these loop region sequences and selecting those that exhibit nuclear receptor

binding affinity. *See* Examples 1 and 2; Koide Decl. ¶ 10. For these reasons, one of skill in the art reading the present specification would be fully able to construct monobodies that have nuclear receptor binding affinity from fibronectin tenth Fn3 domains by modifying the AB, BC, and/or FG loop region sequences as claimed, and would fully recognize that applicant was in possession of the claimed polypeptide monobodies.

Finally, applicant notes that the PTO-1449 submitted with the Information Disclosure Statement ("IDS") dated December 18, 2001, has not been returned to the undersigned attorney. A copy of the IDS, form PTO-1449, and date-stamped return postcard (evidencing receipt by the PTO) are attached as Exhibit 2. Applicant requests that the PTO return an initialed copy of the PTO-1449 form with the next communication from the PTO.

In view of all of the foregoing, applicant submits that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

Dated: December 20, 2006

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